

10/509785
DT04 Rec'd PCT/PTO 29 SEP 2004**Amendments to the Claims**

Please cancel Claims 2 and 3. Please amend Claims 1, 4-7, 9-10, 13-17, 19-22, 24-26 and 29-31. Please add new Claims 32-53. The Claim Listing below will replace all prior versions of the claims in the application.

Claim Listing

1. (currently amended) A polynucleotide selected from the group consisting of:
 - (a) a polynucleotide that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or 19; and
 - (b) a polynucleotide that comprises a coding region of the nucleotide sequence of SEQ ID NO: 1 or 18;
 - (c) a polynucleotide comprising galactose transferring activity, said polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or 19, wherein one or more amino acids are substituted, deleted, added, and/or inserted;
 - (d) a polynucleotide comprising galactose transferring activity, wherein said polynucleotide hybridizes with a DNA comprising the nucleotide sequence of SEQ ID NO: 1 or 18 under stringent conditions; and
 - (e) a polynucleotide that encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or 19.
- 2-3. (cancelled)
4. (currently amended) A vector that comprises the polynucleotide of claim 1 ~~any one of claims 1 to 3.~~
5. (currently amended) A host cell that comprises the polynucleotide of claim 1 ~~any one of claims 1 to 3 or the vector of claim 4.~~
6. (currently amended) A polypeptide encoded by the polynucleotide of claim 1 ~~any one of claims 1 to 3.~~

7. (currently amended) A method for producing ~~the~~ a polypeptide of claim 6 encoded by the polynucleotide of claim 1, which comprises the steps of:
culturing ~~the host cell of claim 5~~ a host cell, wherein said host cell comprises the polynucleotide of claim 1 or a vector comprising the polynucleotide of claim 1; and
recovering the polypeptide produced from the host cell or the culture supernatant of the same.
8. (original) An antibody that binds to the polypeptide of claim 6.
9. (currently amended) A pharmaceutical composition for treating a patient who requires an increase in the activity or expression of ~~the~~ a polypeptide of claim 6 encoded by the polynucleotide of claim 1, wherein the composition comprises a therapeutically effective amount of a molecule selected from the group consisting of:
 - (a) the polynucleotide of ~~any one of claims 1 to 3~~ claim 1;
 - (b) ~~the~~ a vector of claim 4 comprising the polynucleotide of claim 1; and
 - (c) ~~the~~ a polypeptide of claim 6 encoded by the polynucleotide of claim 1.
10. (currently amended) A pharmaceutical composition for treating a patient who requires suppression of the activity or expression of ~~the~~ a polypeptide of claim 6 encoded by the polynucleotide of claim 1, wherein the composition comprises a therapeutically effective amount of a molecule selected from the group consisting of:
 - (a) ~~the an~~ antibody of claim 8 that binds to a polypeptide encoded by the polynucleotide of claim 1; and
 - (b) a polynucleotide that suppresses the expression of an endogenous gene encoding ~~the~~ a polypeptide of claim 6 encoded by the polynucleotide of claim 1 *in vivo*.
11. (original) A method of screening for a candidate therapeutic compound for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, or abnormal activity of the polypeptide of claim 6, which comprises the steps of:
 - (a) contacting a test compound with the polypeptide of claim 6;
 - (b) measuring the galactose transferring activity of the polypeptide of claim 6; and

- (c) selecting a compound that changes the galactose transferring activity, compared to when the test compound is not contacted.
12. (original) A method of testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, or abnormal activity of the polypeptide of claim 6, which comprises the step of detecting a mutation in the gene or its expression control region, in a patient.
13. (currently amended) The A method of ~~claim 12~~ testing for a disease related to abnormal expression of a gene encoding the polynucleotide of claim 6, or abnormal activity of the polypeptide of claim 6, said method comprising detecting in a patient a mutation in the gene or its expression control region, which comprises the steps of:
- (a) preparing a DNA sample from a subject;
 - (b) isolating a DNA that encodes the polypeptide of claim 6 or its expression control region;
 - (c) determining the nucleotide sequence of the isolated DNA; and
 - (d) comparing the nucleotide sequence of the DNA of step (c) with that of a control.
14. (currently amended) The A method of ~~claim 12~~ testing for a disease related to abnormal expression of a gene encoding the polynucleotide of claim 6, or abnormal activity of the polypeptide of claim 6, said method comprising detecting in a patient a mutation in the gene or its expression control region, which comprises the steps of:
- (a) preparing a DNA sample from a subject;
 - (b) cleaving the prepared DNA sample with a restriction enzyme;
 - (c) separating the DNA fragments by size; and
 - (d) comparing the size of the detected DNA fragments with that of a control.
15. (currently amended) The A method of ~~claim 12~~ testing for a disease related to abnormal expression of a gene encoding the polynucleotide of claim 6, or abnormal activity of the polypeptide of claim 6, said method comprising detecting in a patient a mutation in the gene or its expression control region, which comprises the steps of:

- (a) preparing a DNA sample from a subject;
 - (b) amplifying a DNA that encodes the polypeptide of claim 6 or its expression control region;
 - (c) cleaving the amplified DNA with a restriction enzyme;
 - (d) separating the DNA fragments by size; and
 - (e) comparing the size of the detected DNA fragments with that of a control.
16. (currently amended) The A method of ~~claim 12~~ testing for a disease related to abnormal expression of a gene encoding the polynucleotide of claim 6, or abnormal activity of the polypeptide of claim 6, said method comprising detecting in a patient a mutation in the gene or its expression control region, which comprises the steps of:
- (a) preparing a DNA sample from a subject;
 - (b) amplifying a DNA that encodes the polypeptide of claim 6 or its expression control region;
 - (c) dissociating the amplified DNA into a single strand DNA;
 - (d) separating the dissociated single strand DNA on non-denaturing gel; and
 - (e) comparing the mobility of the separated DNA on the gel with that of a control.
17. (currently amended) The A method of ~~claim 12~~ testing for a disease related to abnormal expression of a gene encoding the polynucleotide of claim 6, or abnormal activity of the polypeptide of claim 6, said method comprising detecting in a patient a mutation in the gene or its expression control region, which comprises the steps of:
- (a) preparing a DNA sample from a subject;
 - (b) amplifying a DNA that encodes the polypeptide of claim 6 or its expression control region;
 - (c) separating the amplified DNA on a gel that comprises a gradually increasing concentration of a DNA denaturant; and
 - (d) comparing the mobility of the separated DNA on the gel with that of a control.
18. (original) A method of testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, which comprises the step of detecting the expression level of the gene in a subject.

19. (currently amended) The A method of ~~claim 18~~ testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, said method comprising detecting in a subject the expression level of the gene, which comprises the steps of:
- (a) preparing an RNA sample from a subject;
 - (b) measuring the amount of RNA that encodes the polypeptide of claim 6 comprised in the RNA sample; and
 - (c) comparing the measured amount of RNA with that of a control.
20. (currently amended) The A method of ~~claim 18~~ testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, said method comprising detecting in a subject the expression level of the gene, which comprises the steps of:
- (a) providing a cDNA sample prepared from a subject, and a board on which a nucleotide probe that hybridizes with a DNA encoding the polypeptide of claim 6 is immobilized;
 - (b) contacting the cDNA sample with the board;
 - (c) measuring the expression level of a gene encoding the polypeptide of claim 6 comprised in the cDNA sample, by detecting the intensity of hybridization between the cDNA sample and the nucleotide probe immobilized on the board; and
 - (d) comparing the measured expression level of the gene encoding the polypeptide of claim 6 with that in a control.
21. (currently amended) The A method of ~~claim 18~~ testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, said method comprising detecting in a subject the expression level of the gene, which comprises the steps of:
- (a) preparing a protein sample from a subject;
 - (b) measuring the amount of the polypeptide of claim 6 comprised in the protein sample; and
 - (c) comparing the measured amount of the polypeptide with that of a control.

22. (currently amended) The method of ~~any one of claims 12 to 21~~ claim 12, wherein the disease is IgA nephropathy or Tn syndrome.
23. (original) An oligonucleotide comprising at least 15 nucleotides that hybridizes with a DNA encoding the polypeptide of claim 6 or an expression control region thereof.
24. (currently amended) A drug comprising ~~the~~ an oligonucleotide of claim 23, for testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, or abnormal activity of the polypeptide of claim 6, said oligonucleotide comprising at least 15 nucleotides that hybridizes with a DNA encoding the polypeptide of claim 6 or an expression control region thereof.
25. (currently amended) A pharmaceutical comprising ~~the~~ an antibody of claim 8 that binds to the polypeptide of claim 6, for testing for a disease related to abnormal expression of a gene encoding the polypeptide of claim 6, or abnormal activity of the polypeptide of claim 6.
26. (currently amended) The pharmaceutical of claim 24 ~~or 25~~, wherein the disease is IgA nephropathy or Tn syndrome.
27. (original) A genetically altered non-human animal wherein the expression of C1Gal-T2 protein is artificially altered.
28. (original) A genetically altered non-human animal into which an exogenous polynucleotide that encodes C1Gal-T2 protein has been introduced.
29. (currently amended) The genetically altered non-human animal of claim 27 ~~or 28~~, wherein the non-human animal is a mouse.
30. (currently amended) A cell established from the genetically altered non-human animal of ~~any one of claims 27 to 29~~ claim 27.

31. (currently amended) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) administering a test compound to the genetically altered non-human animal of claim 27 ~~any one of claims 27 to 29, or contacting the test compound with the cell of claim 30;~~
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the genetically altered non-human animal ~~or the cell~~; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
32. (new) A host cell that comprises the vector of claim 4.
33. (new) The method of claim 13, wherein the disease is IgA nephropathy or Tn syndrome.
34. (new) The method of claim 14, wherein the disease is IgA nephropathy or Tn syndrome.
35. (new) The method of claim 15, wherein the disease is IgA nephropathy or Tn syndrome.
36. (new) The method of claim 16, wherein the disease is IgA nephropathy or Tn syndrome.
37. (new) The method of claim 17, wherein the disease is IgA nephropathy or Tn syndrome.
38. (new) The method of claim 18, wherein the disease is IgA nephropathy or Tn syndrome.
39. (new) The method of claim 19, wherein the disease is IgA nephropathy or Tn syndrome.

40. (new) The method of claim 20, wherein the disease is IgA nephropathy or Tn syndrome.
41. (new) The method of claim 21, wherein the disease is IgA nephropathy or Tn syndrome.
42. (new) The pharmaceutical of claim 25, wherein the disease is IgA nephropathy or Tn syndrome.
43. (new) The genetically altered non-human animal of claim 28, wherein the non-human animal is a mouse.
44. (new) A cell established from the genetically altered non-human animal of claim 28.
45. (new) A cell established from the genetically altered non-human animal of claim 29.
46. (new) A cell established from the genetically altered non-human animal of claim 43.
47. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
 - (a) administering a test compound to the genetically altered non-human animal of claim 28;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the genetically altered non-human animal; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
48. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
 - (a) administering a test compound to the genetically altered non-human animal of claim 29;

- (b) measuring the activity or expression level of C1Gal-T2 protein in the genetically altered non-human animal; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
49. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) administering a test compound to the genetically altered non-human animal of claim 43;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the genetically altered non-human animal; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
50. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) contacting a test compound with the cell of claim 30;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the cell; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
51. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) contacting a test compound with the cell of claim 44;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the cell; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
52. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) contacting a test compound with the cell of claim 45;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the cell; and

- (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.
53. (new) A method of screening for a compound that changes the activity of C1Gal-T2 protein, which comprises the steps of:
- (a) contacting a test compound with the cell of claim 46;
 - (b) measuring the activity or expression level of C1Gal-T2 protein in the cell; and
 - (c) selecting a compound that changes the activity or expression level of C1Gal-T2 protein by comparison with activity in the absence of the test compound.